REMARKS

Upon entry of this amendment, claims 2-6, 8-10, 12-19, 22-26, and 33-35 will be pending and examined on the merits. Claims 14 and 16 have been amended and claims 1, 7, 11, 20, 21, and 27-32 have been withdrawn from consideration. Applicants respectfully request reconsideration and allowance of the application.

Objections to Claims

The Office Action has objected to claims 14 and 16 for reciting non-elected subject matter. Claims 14 and 16 have been amended to delete the pCWin1 vector of Group 1 from claims 14 and 16. No new matter has been added. Applicants respectfully submit these objections have been obviated and respectfully request reconsideration and withdrawal of these objections.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 2-6, 8-10, 12-19, 22-26, and 33-35 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement.

The Office Action states that the specification does not disclose a repeatable process to obtain essential "biological material and it is not apparent if the biological materials are readily available to the public." Office Action at page 3. Specifically, the Office Action states that there is no evidence that the pCWori vector used in the preparation of the pCWin2 expression vector is commonly or publicly available. Office Action at page 3. Applicants respectfully traverse the rejection.

Applicants enclose herewith evidence that pCWori plasmid is readily available. Paragraph [0117] of the present specification refers to one source of the plasmid as described in Muchmore et al, 1989, Meth Enzymol, 177:44-73. Additional and numerous sources of the plasmid are illustrated in the attached search results from several science databases (MedLine, BIOSIS, EMBASE, Agricola and Sci Search available from Dialog)

(*see* Attachment 1). Referring to Attachment 1, pCWori has been used at universities and in corporate environments, and throughout the world, from the US to Israel to Russia to Japan (*e.g.*, at Purdue Pharma LP, Stamford, Connecticut, USA; Himeji Institute of Technology, Japan; Israel Oceanographic and Limnological Research, Haifa, Israel; National Institute of Health, Research Triangle Park, NC; Osaka City University Medical School, Osaka, Japan; Institute of Biological Chemistry, Washington State University, Pullman, Washington; Institute of Biomedical Chemistry RAMS, Moscow; University of Texas Medical School at Houston, Houston, Texas; Louisiana State University, Baton Rouge; University of California, San Francisco etc).

Moreover, detailed review of select publications, establishes that the plasmid pCWori is shared without restrictions (*see e.g.* Attachments 2-5). Thus, see, for example:

(i) Fisher *et al.,* High-level expression of functional human cytochrome P450 1A2 in Escherichia coli; FASEB J. 1992 Jan 6;6(2):759-64 (Department of Biochemistry, University of Texas Southwestern Medical Center, Dallas) obtained the plasmid from Amy Roth, Department of Biochemistry, University of Oregon (*see* page 759, col. 2, last par);

(ii) Gerber and Ortiz de Montellano, Neuronal nitric oxide synthase. Expression in Escherichia coli, irreversible inhibition by phenyldiazene, and active site topology, J Biol Chem. 1995 Jul 28;270(30):17791-6 (Department of Pharmaceutical Chemistry, School of Pharmacy, University of California, San Francisco) obtained the plasmid from Robert Fletterick, University of California, San Francisco (*see* page 17792, col. 1, 1st par. under "Materials");

(iii) Sibbesen *et al.,* Putidaredoxin reductase-putidaredoxin-cytochrome p450cam triple fusion protein. Construction of a self-sufficient Escherichia coli catalytic system, J Biol Chem. 1996 Sep 13;271(37):22462-9 (Department of Pharmaceutical Chemistry, School of Pharmacy, University of California, San Francisco) obtained the plasmid from Eric Johnson from Scripps Institute (*see* page 22463, col. 1, 1st par. under "Materials and Methods"); and

(iv) Barnes *et al.,* Expression and Enzymatic Activity of Recombinant Cytochrome P450, Proc. Natl. Acad. Sci, 1991:88,5597-5601 (University of Texas Southwestern Medical Center) obtained the plasmid from Michelle Browner of UC California, San Francisco (*see* pahe 5601, col. 1, last par).

Additionally, Applicants draw to the examiner's attention to the link http://www.addgene.org/pgvec1?f=c&cmd=findpl&identifier=20117 that demonstrates the availability of the pCWori backbone vector that is made publically available for purchase as the vector backbone of the Plasmid 20117: pCWori-A13AMO-aaCPRct. A copy of this page is attached as Attachment 6.

Regarding the construction of the pCWin2 vector recited in the present claims, detailed guidance is provided by the Applicants' specification, for example, at paragraphs [0118] to [0122] and in the examples starting at paragraph [0177] for making and using the pCWin2 expression vector starting with the pCWori plasmid, which is (as discussed above) commonly available.

In view of the above and the attached evidence, Applicants respectfully submit that the specification provides sufficient guidance to a person of skill in the art to practice the claimed invention without undue experimentation and request reconsideration and withdrawal of this rejection.

Respectfully submitted,

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